November 10, 2015
Outline of CITMA Comments to OIRA on Deeming Regulation

Economic Impact on Cigar and Pipe Tobacco Small Businesses

- The marketplace for cigars and pipe tobacco consists of many small manufacturers and importers with many low-volume SKUs in many configurations to meet varied consumer demand.
- Small cigar manufacturers comprise a very small portion of the total share of the market (17% total), with each company having an average market share of .0008%, but there are many small companies in the cigar market. See attached spreadsheet.
- The vast majority of cigar and pipe tobacco companies are small manufacturers.
- FDA has greatly underestimated the total number of regulated entities because it did not take into account importers and manufacturer of components of tobacco products.
- A significant number of companies in the cigar and pipe tobacco segment, particularly small businesses, entered the market after February 15, 2007.
- Because a large number of small manufacturers entered the market after February 15, 2007, they do not have access to adequate predicates for the SE process.
- In initial results from a survey of small cigar manufacturers (17 companies responded; 1,414 employees total), the companies identified 2,236 SKUs that would be regulated by FDA, but were able to identify only 175 predicates (8% of SKUs). The respondents indicated that they would likely try to file approximately 657 SE reports (29% of SKUs), but due to the limited number of predicates and FDA's overly demanding approach to SE reviews, it is anticipated that a significant number of these will be unsuccessful. See attached survey information.
- Based on TTB filings, we estimate approximately 11,000 to 27,000 individual SKUs in the current cigar marketplace.
- Purchasing sufficient information about even a single predicate product to meet FDA's current SE standards, if even an option, would be prohibitively expensive for most small manufacturers, with no certainty that they would be granted a marketing order.
- As it has evolved since the enactment of the TCA, the SE process has become overly onerous and would be virtually impossible for small cigar manufacturers to navigate in light of the unique nature of the cigar manufacturing process and the large number of cigar variations. See attached SE White Paper.
- Member examples (e.g., Rock River Manufacturing Company) of SE experience
- The initial results from the survey of small cigar manufacturers referenced above indicate that:
    - 11 of 17 respondents felt their company may be able to survive but most stated that this was due to other tobacco product lines.
    - The 17 respondents predicted approximately 369 job losses, which is a labor force reduction of 26%.
- Astronomical costs of HPHC testing (per cigar cost is 5079% higher than per cigarette cost). See attached spreadsheet.

Economic Impact on ENDS Small Businesses

- The vast majority of the ENDS marketplace consists of small local businesses, many in smaller communities with limited employment opportunities.
- The absence of adequate predicates for ENDS products to utilize the SE process means that each ENDS product would be required to be the subject of a full PMTA.
- This means that virtually every individual product currently on the market (e.g., each flavor, nicotine level, packaging configuration, etc.)—and each future product developed by industry—will require individual approval via the PMTA pathway.
- Even with clear guidance from FDA, the cost of preparing a PMTA application could exceed a million dollars per product. Our initial PMTA cost estimates, based on an analysis by SciLucent, LLC, of the September 2011 draft guidance ranges from $1.3 million to $3.5 million per new product. If you assume the average company offers three distinct e-cigarette devices and 20 distinct e-liquids, the costs could exceed $75 million dollars to develop the requisite PMTA applications per company.
- In a survey of 293 members of the Smoke Free Alternatives Association (SFATA) who market ENDS products, only one respondent indicated that it might be able to stay in business were PMTAs for each of their products required. See attached survey information. A handful of entities indicated that they might be able to afford to file at least one PMTA at FDA's too-low estimated cost of $333,554, but even those companies could not remain viable with only one or even a few SKUs on the market. In the survey, the respondents noted:
    - Some market thousands of unique SKUs, including different flavors and nicotine levels in e-liquids, as well as various devices and components.
    - Many manufacture products by hand and in small batches.
    - Many are family-owned businesses and their family's livelihood is dependent on the viability of the business.
    - Most pay a living wage to their employees, who may not have other employment options to support their families.
- The PMTA process would therefore eliminate virtually all small manufacturers. FDA states as much in its RFA for the proposed deeming regulation, acknowledging that it expects to receive only 25 PMTAs, which represents only 1.5% of the number of SKUs FDA estimated were on the market in this category. CITMA believes FDA's SKU figure underestimated the actual number of SKUs on the market to a significant degree. Thus, the percentage of SKUs in the market reflected in FDA's estimate for PMTAs received likely falls well below 1%. We identified over 140,000 SKUs in our survey.
- Imposing the existing expensive and onerous PMTA regime on ENDS products, without the flexibility to account for the potential public health benefits such products could offer to smokers, could effectively hand the market to an oligopoly of large legacy tobacco manufacturers who have the resources from their sales of combustible products to finance such a process. Interestingly, the large tobacco companies currently offer approximately 25 SKUs of ENDS products, which is the number of PMTAs FDA expects to receive.

- The results of the current proposal thus could include dramatic market consolidation, job losses, elimination of small businesses, significant reductions in consumer choice and innovation, and a remigration of ENDS users back to combusted cigarettes as the large tobacco companies have no interest in selling the less profitable ENDS products, especially if they can transition customers back to combustible tobacco products.
- Extending the compliance deadline for small businesses will not sufficiently reduce the burdens on small businesses; it will merely delay the removal of these businesses from the marketplace.

Unintended Consequences of ENDS Regulation

- Small businesses are often the types of entities that are at the forefront of product innovation, as FDA has seen repeatedly in the drug and device industry and is the case in the ENDS industry.
- If final regulations are not modified from the proposal, the marketplace will be shifted to the largest and most financially secure companies who are likely to be primarily marketers of combustible tobacco products. These companies may not have the same incentives to continue to advance the technology of novel and lower risk tobacco products that could cannibalize sales of their more-profitable combustible products.
- Removal of small businesses from the marketplace, thereby restricting the market for ENDS products, will have the unintended consequence of forcing millions of consumers back to smoking traditional cigarettes. Given the prevailing scientific opinion that non-combusted forms of nicotine are far safer than combusted cigarettes, FDA's proposal could prove devastating to the public health.
- The potential for tobacco harm reduction products, such as ENDS, to reduce the burden of smoking-related disease (i.e., reduced deaths, improved productivity, lower health care costs) may be very significant. FDA should not suppress this technology with overly burdensome regulation before its benefits have been fully realized.

Key Items for Change

1. Change Grandfather Date: FDA could use its enforcement discretion or rulemaking authority to move the February 15, 2007, date to the date of publication of the final deeming regulations, thus eliminating the most burdensome tasks of navigating the SE and PMTA processes for products that are currently on the market. Using FDA's enforcement discretion in this manner does not undermine the Agency's stated mission of protection of public health, as these products would still be subject to many other regulatory requirements. In addition, other categories of tobacco products, including combustible cigarettes, will be available to consumers regardless of the ability of small manufacturers to comply with the deeming regulations. This would also free up needed resources so the FDA can more quickly begin the process of developing product standards, testing standards, and GMPs. Finally, this would maintain competition in the marketplace as, without this change, only the large manufacturers would likely survive.

2. Product Standards Rather than Premarket Approval for ENDS Products
   - Rather than applying the PMTA regime that Congress designed for traditional tobacco products to ENDS products, FDA should instead exercise its broad enforcement discretion to not require premarket submissions for ENDS products that meet product standards promulgated by FDA.
   - Based on the continuum of harm repeatedly acknowledged by FDA, and the growing body of evidence that ENDS products are a less harmful alternative to combustible products, FDA can conclude that permitting ENDS products that meet certain product standards to remain on the market would be "appropriate for the protection of public health."
   - Companies would be responsible for determining that their product meets the applicable product standards (when effective) in order to keep it on the market. Products that fail to meet the product standards would be subject to enforcement action for failure to comply with applicable standards and premarket review requirements. FDA could require the filing of a tobacco product standard compliance statement under penalty of perjury.
   - Timely implementation of basic product standards could benefit the public health faster and more effectively than a premarket approval system with a 24 month compliance period followed by a review period. For example, FDA could quickly limit the use of harmful ingredients such as diacetyl in e-liquids.
   - Companies must file an abbreviated PMTA for ENDS products that deviate from the product standards.
   - FDA should permit continued marketing of ENDS products until promulgation of final product standards with a compliance period allowing for product redesign or reformulation to meet such standards or submission of an abbreviated PMTA.
   - Like the OTC Review, this would enable the Agency to protect the public health in an efficient manner without requiring full PMTA submissions for each individual product, a process that could bring the Agency to a virtual standstill and decimate the marketplace for the smaller industry players.
   - Industry could assist FDA with convening expert panels to establish flavor standards for ENDS products.

3. Abbreviated PMTA Pathway: In addition or in the alternative, FDA could develop an abbreviated PMTA pathway for ENDS products. See attached Streamlined Pathways White Paper.

4. Develop Standard Reference Products for Use as "Predicates" in SE Process: Instead of requiring each SE report to cite an individual predicate that was on the market on an arbitrary date in 2007, almost 9 years ago, FDA – with the assistance of industry – should establish standard reference products for companies to cite in SE reports. See attached Streamlined Pathways White Paper.

5. Allow Minor Changes to Deemed Products: As in the medical device context, FDA could use its enforcement discretion to require new SE reports only for certain

modifications rather than strictly enforcing the "new tobacco product" definition to include any and all changes, no matter how insignificant. A new SE order should be required only where the modifications could significantly affect the risks presented by the product and FDA should provide specific guidance for manufacturers to conduct this analysis internally. See, e.g., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm. It is also essential that FDA permit package quantity changes without requiring SE review or behavioral data to support such minor routine packaging changes.

6. Delayed Compliance Dates Tied to Publication of Final Guidance: If FDA provides for delayed compliance dates, the deadline for submissions such as PMTAs, SE reports and HPHC testing reports should be set on the date that is 24 months from FDA's publication of final guidance relating to the particular filing for the specific category of deemed products. Thus, for example, in order for a company to be covered by FDA's compliance policy, a SE report for a cigar product would be due 24 months from the date of publication of a final guidance specifically relating to the content of SE reports for such products. If FDA follows this approach, SE reports for cigar products will be of higher quality, which will reduce the Agency's workload and expedite the review process.

7. Narrowly Define Regulated Tobacco Products: FDA has proposed to regulate as tobacco products components and parts of tobacco products, but not accessories to deemed tobacco products. FDA should clearly define these categories to limit the scope of those products subject to FDA's regulatory authority so that the burden of compliance is not overwhelming both to small businesses and to FDA.

Process Concerns

- The leak of the final rule to TVECA raises grave process concerns.
- A small segment of industry's having access to the full text of the final regulation (as well as at least one companion guidance document), even if still in draft form and under review, places other stakeholders, including CITMA members, at a significant disadvantage.
- CITMA has requested that FDA immediately release to the public a copy of all leaked materials in the possession of TVECA. See attached letter to Mitch Zeller (November 9, 2015).
- Once the leaked documents are released to the public, CITMA requests the opportunity to schedule another meeting with OIRA.

Cigar Category	**Per TTB Report**	
Total Cigars December 2013	13,162,168,668	
Per the USDA Report 225 Cigar Companies		
Top 10 Cigar Companies Market Share is	61.21%	
Next 10 Cigar Companies Market Share #11-20 on USDA	21.93%	
Top 20 companies have	83.13%	
Remaining 205 Market Share	16.87%	
Average market Share of these 205 companies is	0.000822688	
FDA states 11449 to 12971 Cigar SE Applications if we avereage	12210 SKUS	
Per Company SKUs	54	
Our Survey Showed per SKU by Company averaged	132	
Small companies usually offer a much wider array of products		
Likely Range of SKUs by the 205 very small cigar companies	11070-27,060	Based on 205 at 54 SKUs and 205 a
Average for a Small Company	93	

Pipe Category	Per 2013 TTB Report
Total Pounds of Pipe Tobacco	42,273,574
Per the USDA Report 94 Pipe Companies	
Top 10 Pipe Companies Market Share is	71.72%
Next 84 Pipe Companies	28.28%

Average market Share of these 84 companies is	0.3366%
FDA states 924 to 1059 Cigar SE Applications if we avereage	992 SKUs
Per Company SKUs	10.55

SUMMARY OF CIGAR SURVEY FINDINGS

17 companies responded

1,414 employees in all companies

Identified 2,236 SKUs that would be regulated by the FDA

Identified 175 predicates for this 2,236 SKUs

Would file 657 Substantial Equivalence reports

11 of 17 companies felt they would survive process but only due to other tobacco product lines in portfolio

369 job losses

Key Takeaways

Labor force would be reduced by 26%

Only 8% of products have adequate predicates (products on the market on February 15, 2007) with which to file an SE report

Companies state they will file 657 SE Reports or 29% of total SKUs but will be using predicates that likely do not meet the required standard for approval

Of the companies that said they could survive process, they based survival on overall financial strength of the rest of their companies' portfolios.

SUMMARY OF VAPOR PRODUCT SURVEY FINDINGS

293 companies responded

2,389 employees in all companies (~8 per business)

1935 total device SKUs

140,141 total e-liquid SKUs

When asked how many Pre-Market Tobacco Product Applications company could afford to file given the following cost estimates:

$333,000 (FDA estimated cost) – 86 applications

$500,000 – 35 applications

$750,000 – 18 applications

$1,000,000 – 12 applications

$2,000,000 – 3 applications

The most applications a given company stated it could file was only 10. The vast majority were obviously 0.

Only one company of the 293 responding stated they might be a viable company assuming the FDA approves their PMTAs.

Questions for Cigars, Pipe and Hookah

Question 1:
How many employees (Full Time equivalents = 30 hours or more do you employ?

Question 2:
How many new SKUs will you be required to file for each of the following categories (See definition of a New Product) remember that all different flavors, sizes and quantities are a Unique SKU

Pipe tobacco
Cigars
Hookah
Other tobacco products

Question 3:

How many predicates to you believe you have for each of the following categories based on your answer above and how you know realize the exacting sprecifications placed on SE approval by the FDA

Pipe tobacco
Cigars
Hookah
Other tobacco products

Question 4:

FDA Estimates that to file a single SE application the costs per SE application will be $19,421 but does not include any testing cost But use this as the guage as I do not think the cost will be the prohibitive issue it will be having a suitable prediate.

If the costs for each SE application that outlined above how many SE applications will you likely file for each of the following categories:

Pipe tobacco
Cigars
Hookah
Other tobacco products

Question 5:

If the FDA approves all of the SE Applications you stated you
would be able to file in question 4 above will you remain
a viable company in the following segments (yes or no only please)

Pipe tobacco
Cigars
Hookah
Other tobacco products

Question 6:

Based on the answer to question 5 above how many full time employees, if any,
would lose their jobs based on the number of SE applications
you anticipate would be approved

Details regarding certain Questions on the Survey

Question 1:

When answering this question please considering all employees working 30 or more hours to be a full time employee.

Question 2:

New Product SKUs – A new product is defined as a tobacco product that was either not commercially marketed on February 15, 2007 or was commercially marketed on February 15, 2007 but has subsequently been changed. A change encompasses any minor changes to the product itself and in some cases packaging changes per the FDA.

Unique SKUs – The FDA seems to take the position that products that are the same yet offered to the consumer in different quantities or sizes are unique and require a separate SE filing. For example, if you have a cigar that is sold in 2, 3 and 4 pack that is 3 unique SKUs. Also, if you offer a pipe blend in 3 oz., 6oz and 8 oz. that is 3 unique blends and the same is true for the same hookah product in different gram weights.

Question 3:

When determining if you have an appropriate predicate with a high likelihood of FDA approval please only consider predicates where you have the same or very, very similar characteristics and the same flavor profile. Also, only consider predicate that you either own or have full access to the information about the product from 2007 as we have seen the FDA is pushing back on predicates whereby information unrelated to the actual product is self is missing such as how manufactured etc. and could deny such an application.

Question 4:

This question should be considered in 2 parts. First, strictly can you even afford the cost to file the SE for one or more products? Secondly, you should evaluate if the sales of the current product justify filing an SE for a particular SKU.

Question 5:

Base your answer to this question on the total number of SE applications you believe you could get approved and then take into account the ability to maintain and possibly grow the sales of these particular SKUs to see if you would be a viable company in these segments. Please look at this question outside of your currently regulated business should you currently sell cigarettes, RYO and smokeless tobacco.

Question 6:

Please respond based on the likelihood that you will have to release some employees based on the number of SE applications you believe you will get approved.

Request edit access

Survey of E-Cigarette or E-Liquid Products for FDA Regulation

The purpose of this survey is to demonstrate to the Small Business Administration (SBA) that small companies will be severely adversely affected by the implementation of the FDA deeming regulations, expected to be released later this year, by forcing companies that manufacture E-Products to use a Pre-Market Tobacco Application (PMTA) pathway to obtain approval to market such products.

By the by FDA's own account the cost of filing a PMTA will likely ruin all small competitors in the marketplace. This survey is meant to be anonymous and you will note that no question asks you to identify your company or your brand names.

Your response will be added to that of as many small manufacturers of E-Products as possible to show the SBA that small companies need their assistance to intervene with the FDA and push the FDA to change the process by which companies will be required to get their products approved to be marketed by the FDA.

Again, please remember that no company specific information will be released and none of the questions below ask you to identify your company or brands but your participation in this survey is extremely important.

We also break the questions out into devices and liquids as many manufacturers that carry devices do not make the devices themselves and will thus be dependent on their manufacturer to submit the necessary information to the FDA. Finally, it is important to note that when we ask you questions regarding the number of SKUs or styles you manufacture you should include for e-liquids for example, every flavor, strength of nicotine, and bottle size in your answers. Therefore, if you have the flavor apple, in 5 nicotine strengths (do not count 0 nicotine products) in 3 different sizes you have 15 SKUs for just this one flavor. You should also make sure that you include all of the brands you manufacture in your total SKUs. If you have someone make your liquids for you then you should send them this survey to them and ask that they complete it as well to get as much information as we can.

Finally, we do ask two questions that discuss the financial ability of your company to survive the FDA process. These questions however, while specific to you, are still very general in terms of your business.

* Required

How many employees does your business have? *

This question is asked as we need information only from manufacturers that have fewer than 350 employees as that is the definition of a small tobacco manufacturer in the FDA law and whose information we want to present to the SBA. We also want the FDA to know how many jobs could be lost by these regulations.

How many different devices (SKUs of devices) do you manufacture? *

Answer this question only if you manufacture your device and it's a full device not components such as batteries or coils etc. You should include pre-filled cartridges and tanks in this SKU count if you manufacture them.

How many different e-liquids do you manufacture? *

Remember you are a manufacturer by law if you mix, bottle or label the product. Remember when answering this question to include every unique Brand, flavor, bottle size and nicotine strength, except 0 nicotine in your total SKU count. This is basically how many different e-liquids you manufacturer.

Total number of SKUs for both devices and E-Liquids? *

The sum of the last two questions

Based on the cost PER-SKU outlined below, how many SKUs can your company afford to file the Pre-Market Tobacco Application form with the FDA under the following circumstances:

If the cost were $333,554 (actual estimate by the FDA) per SKU, I could afford to submit this many Pre-Market Tobacco Applications:

If the cost were $500,000 per SKU, I could afford to submit this many Pre-Market Tobacco Applications:

If the cost were $750,000 per SKU, I could afford to submit this many Pre-Market Tobacco Applications:

If the cost were $1,000,000 per SKU, I could afford to submit this many Pre-Market Tobacco Applications:

If the cost were $2,000,000 (estimate by Scientists as outlined in the WSJ) per SKU, I could afford to submit this many Pre-Market Tobacco Applications:

Based on the number of PMTAs you could afford to file with the FDA, and that number of PMTA were actually approved, would you still be a viable company, yes or no? *

This question is simply asking for the number of SKUs that you stated you could afford to file PMTAs with the FDA, would your sales of that number of SKUs be enough to continue to operate your company on a financial stable basis. Please provide as much information as you care to share.

Submit

Never submit passwords through Google Forms.

CITMA 11/10/2015

WHITE PAPER: THE SUBSTANTIAL EQUIVALENCE PROCESS TO DATE

Section 905(j) of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides an "expedited" pathway to bring to market a new tobacco product that is "substantially equivalent" (SE) to a "predicate product," i.e., a product that was on the domestic market "as of" February 15, 2007 (or another product that FDA has determined to be substantially equivalent to a product on the market "as of" February 15, 2007). *See* 21 U.S.C. §§ 387j(a)(2)(A)(i), 387e(j)(1)(A)(i). "Substantially equivalent" means that the tobacco product at issue either: (1) has the same characteristics as the predicate product; or (2) has different characteristics, but the information submitted in the applicant's report demonstrates that the differences do not raise different questions of public health. 21 U.S.C. § 387j(a)(3)(A). Congress intended the substantial equivalence process to be a streamlined "notification" process,[1] one that would be less onerous and more expeditious than a full premarket approval process. Indeed, the FFDCA states that SE reports must be submitted "at least 90 days prior to" introducing a new tobacco product into interstate commerce. 21 U.S.C. § 387(j)(1). This provision was modeled after the 510(k) device review process that requires FDA to conduct its review within 90 days. *See* 21 U.S.C. § 360(n).

Nevertheless, now roughly 55 months since the first industry report was filed, the substantial equivalence review process continues to be increasingly burdensome, arbitrary, and inconsistent with statutory intent. Thousands of SE reports remain pending at FDA, most for over 4 years since filing. Only 15% of the 3591 provisional[2] reports filed by March 22, 2011, have been resolved, a significant number of which by the applicant's own withdrawal. FDA continues to request that SE applicants submit information not expressly required under the FFDCA or FDA's implementing regulations, described in any Agency guidance document or webinar, or even requested in previous reviews of SE reports seeking authorization to make similar or identical modifications to the cited predicate products. Indeed, the Agency still refuses to provide industry with adequate guidance concerning how the Agency will apply the statutory standards and what information companies must provide in SE reports.

Lack of Guidance

FDA's requirements relating to the content of SE reports have been a constantly moving target. The Agency has requested new and different information over time, even from the same company for the same modifications in different reports. FDA continues to add new requirements retroactively to previously filed SE reports, sending applicants requests for additional and more specific information, most of which has never been articulated in any written or oral FDA guidance to industry.

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[1] *See* 21 U.S.C. § 387j(a)(4)(A).

[2] The term "provisional" report refers to an SE report filed for a product introduced or modified between February 15, 2007, and March 22, 2011, for which the manufacturer submitted an SE report on or before March 22, 2011. A product subject to such a report may remain on the market pending FDA review of the report. *See* 21 U.S.C. § 387j(a)(2)(B). In the event FDA issues a negative order in response to a provisional SE report, the interim marketing exception ceases to apply to the subject product, which then must come off the market.

Indeed, FDA has thus far provided very little industry guidance and instead appears to be regulating company by company and report by report in a completely arbitrary fashion. The Agency has publicly posted documents from reviews of successful SE reports, documents from reviews of unsuccessful provisional SE reports, and summary information about its bases for issuing not substantially equivalent (NSE) orders in response to regular (i.e., non-provisional) SE reports for products not yet on the market. However, most of the specific information in the review documents that would provide relevant and useful direction to industry (e.g., product specifications or other comparative data) has been broadly redacted, offering little, if any, meaningful practical information that would increase industry's understanding of the SE process.

FDA's report-by-report review in the absence of meaningful or specific guidance has resulted in a process that is both arbitrary and capricious and has proved to be too onerous for even the largest tobacco companies, including R.J. Reynolds Tobacco Co. (RJR), which, as discussed below, recently received four NSE orders for provisional SE reports. This is particularly the case in the context of the irrational timeframes FDA has established for manufacturers to respond to information requests, most of which seek voluminous data that have never been described in any FDA guidance document and that many small manufacturers have never created or possessed.

Irrational Timeframes

Although the Agency has announced performance measures[3] for FDA's review of regular SE reports, it claims that it does not yet have enough experience with provisional reports (after 55 months) to establish performance measures for this much larger category of reports. It is not clear why FDA's experience with regular reports is not likewise relevant to provisional reports, which are substantively identical. Moreover, despite its failure to act in a timely manner in reviewing provisional reports, FDA has set draconian deadlines for applicants to respond to detailed and demanding information requests and has issued draft guidance[4] formalizing its policy to refuse to grant extensions to any regular SE report applicant and to most if not all provisional SE report applicants. (While the document remains in draft form, FDA appears to have implemented the policies on extension requests proposed therein.) When manufacturers do file extension requests, FDA often has neglected to respond in a timely manner, thereby vitiating the utility of an extension in any event.

FDA typically allows 30 to 60 days for a response to an Advice and Information Request (AIR) letter and 30 days for response to a Preliminary Finding (PFind) letter to fully address often numerous, complex, duplicative, unclear, or inconsistent technical requests for information, much of which even very sophisticated larger manufacturers do not normally compile on a routine basis. Importantly, these timeframes are, in effect, actually even shorter than the stated numbers of days (that are themselves insufficient) in that:

1. The clock begins to run from the date of the mailed FDA correspondence, which may

[3] *See* Memorandum from CTP Director to CTP Deputy Director (Apr. 18, 2014), *available at* http://www.fda.gov/downloads/tobaccoproducts/newsevents/ucm393908.pdf.

[4] *See* FDA, *(Draft) Guidance for Industry: Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product* (July 2014), *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM404898.pdf.

not be received by the company for several days;
2. The timeframe includes non-business days (e.g., weekends and holidays) and, if the deadline falls on a non-business day, FDA expects to receive the response on the previous business day (a practice that does not follow the standard legal convention of accepting the submission or filing on the next business day);
3. The timeframe terminates upon actual receipt by FDA rather than the date the response is postmarked;
4. FDA has not provided timely responses to companies' requests for clarification or explanation of its information requests, thereby preventing companies from effectively processing responses while they wait to hear back from the Agency; and
5. Many Agency requests are received in the mail with no advance notice, often bundled together with 25-50 separate product requests after several years of inactivity.

Thus, for example, if FDA gave a company 30 days to respond to an information request dated August 29, 2014, FDA's current approach would have required receipt of the response by FDA no later than Friday, September 26, providing the company only 14 business days on which to work on the response in light of the following factors:

- August 29 was a Friday, the following Monday was a federal holiday, and so the company may not have received the letter until perhaps September 4 or 5, depending on its location.
- September 5 was a Friday, and so, if the letter was received in the late afternoon on that day, work could not realistically have begun until the next business day or Monday, September 8.
- 30 days from August 29 was actually September 28, but that is a Sunday, and so the response would need to have been received on the previous Friday (September 26).
- FDA accepts responses only in hard copy format sent to its Document Control Center or via electronic filing, refusing to permit companies to use more convenient and expeditious email or fax. Because the electronic filing system has been virtually non-functional for most small companies, they are required to send responses via overnight mail. Therefore, the response must have been completed and sent by September 25.

For a small company going through the SE process, perhaps for the first time, without the benefit of any up-to-date guidance or access to information disclosed only to other companies in the context of their individual reviews, 14 days is grossly insufficient and unfair. The process of responding to a deficiency letter often involves reviewing and processing the numerous information requests (including determining what requests can and cannot be addressed by internal resources), consulting suppliers and outside experts, developing data and information (including potentially having laboratory work performed by an outside lab with limited capacity), and then preparing and validating the actual response. Where a small company must rely heavily on information from suppliers, consultants, attorneys, and laboratories to respond to FDA requests, meeting an initial deadline can be especially challenging, and whether the company can actually do so remains largely out of its control.

The typically short response deadlines also leave little time for the company to obtain any needed clarification from FDA prior to embarking on this process, and essentially no time if FDA does not respond to the clarification request in a timely manner. If the company attempts to obtain an extension to allow for the extra time needed to obtain a clarification from FDA, or information from consultants or suppliers, it must then allocate some of its limited time and resources during the response period to prepare a detailed extension request. This makes meeting the original deadline more challenging still, particularly where FDA's expectations continue to change and expand over time.

Arbitrary Information Requests

In the absence of sufficient written guidance from FDA that both provides notice to industry regarding FDA's expectations and requires consistency in those expectations, FDA's information requests in the context of SE reviews have been inconsistent, arbitrary, and capricious. What was adequate in one case has proved to be inadequate in another. As but one example, FDA has requested certain data regarding harmful and potentially harmful constituents (HPHC) for both new and predicate products. However, the Agency has asked about different smoke constituents in different reports that cite identical modifications. For a change to state-law-required fire safe cigarette (FSC) paper, for instance, we are aware of at least three different requests for HPHC data: one requested only tar, nicotine, and carbon monoxide (TNCO) data, and an SE order was issued in part on the basis that the values were not significantly different; another additionally requested data for acetaldehyde, formaldehyde, and benzene (in addition to TNCO); and the last requested data for benzo[a]pyrene, acetaldehyde, and benzene (in addition to TNCO). Accordingly, even if all industry members had access to all of these requests, which they do not, they would not know which one to consult for guidance or what to expect from FDA in the context of any individual review.

In addition, in the context of reviewing SE reports for cigarettes, FDA is now requesting "target specifications and upper/lower range limits (i.e., pass/fail criteria)" for as many as twenty-eight "key design specifications/parameters" for both the predicate and new product, as well as "test data confirming that design parameter specifications … are met (i.e., measured values of design parameters), including test protocols, quantitative acceptance (pass/fail) criteria, data sets, and a summary of the results for the design parameters" for both predicate and new product. The "specifications" sought by FDA have continued to expand over time; again, what was sufficient to support an SE order in 2014 is no longer sufficient to support an order in 2015.

Importantly, many of the "specifications" sought by FDA are not truly specifications because most (if not all) cigarette manufacturers do not use these parameters in the manufacturing process and, in the absence of good manufacturing practice (GMP) regulations for these products, are not required to do so. Indeed, most small manufacturers had never heard of some of these parameters when FDA asked about them, and FDA has provided no guidance to industry on this issue. Through this process, FDA has essentially imposed backdoor GMPs while avoiding required notice-and-comment rulemaking. This has not only overly burdened small manufacturers; it appears that even the largest tobacco companies have been unable to develop the documentation sought by FDA in the context of SE reviews.

On September 11, 2015, FDA issued NSE orders to RJR for four of its cigarette products. As the second largest tobacco company in the United States, one would expect that RJR would be able to meet any documentation requirement imposed by FDA. This appears not to be the case. In the Technical Project Lead memoranda for these SE reports, FDA observed that RJR failed to provide target specifications and upper and lower range limits for cigarette band porosity and upper and lower range limits for filter total denier and denier per filament. FDA also asserted that RJR failed to provide full test data to confirm that target specifications for various features were met. In addition, RJR apparently did not "fully characterize" the tobacco blends used in the cigarettes. If RJR is unable to adequately respond to FDA's current information requests during SE reviews, it is unclear how any small manufacturer is expected to navigate the process.

Unreasonable and Potentially Impossible Burden of Proof

Although FDA has not articulated it to industry as a whole, FDA appears to have established a standard for the "different questions of public health" criterion that in many cases industry could never meet, even with unlimited resources. For instance, FDA has imposed on applicants the burden to conclusively rule out any impact on consumer perception or consumer use for all ingredient differences, even those as minor as components of non-characterizing flavors or substituted sweeteners. Indeed, at the outset, FDA appears to presume that all differences in flavoring components (even in products without any characterizing flavor) could enhance product appeal and palatability and therefore influence initiation behaviors, tobacco dependence, and continued use, thereby raising "different questions of public health." The Agency then shifts the burden to the applicant to prove otherwise without any guidance on the nature of the scientific support required to prove this negative.

Even one of the largest tobacco companies in the United States, with its vast resources and in-house scientists, was unable to meet FDA's expectations in this regard. As an example, from the review documents of SE0000281, although largely redacted, it appears that RJR submitted data and information to support the company's position that differences in sweeteners and other non-characterizing flavoring ingredients in the compared cigarette products did not raise different questions of public health. FDA summarily dismissed these data, and its brief explanation for this action is for the most part redacted.

Without any publicly available information from FDA in guidance or elsewhere on how a company might meet its burden of proof in this context, obtaining an SE order for any new product that does not contain the same flavoring ingredients in the same amounts as those in the predicate product, including when the predicate product has a different characterizing flavor,[5] may well be impossible. Again, Congress could not have intended this approach – which operates essentially as a ban on new or different flavors or flavor ingredients – when it established the SE "notification" pathway. This approach can have particularly draconian

[5] *See* FDA, *Brief Summary of "Not Substantially Equivalent Determinations"* (Sept. 15, 2015), *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM462409.pdf ("Addition of a new characterizing flavor may cause the new product to raise different questions of public health because initiation may increase and/or cessation may decrease. Addition of menthol as a characterizing flavor to a predicate product that does not contain menthol as a characterizing flavor. This causes the new product to raise different questions of public health as it relates to initiation, dependence, and cessation.").

impacts when, for example, companies had to change flavoring ingredients after February 15, 2007, due to circumstances completely out of their control (e.g., decisions by suppliers to cease doing business with the industry, discontinuation of supplied ingredients, etc.).

Finally, FDA has taken the position that a change in product quantity in a product package, even if the per weight composition of additives, ingredients, and other features remains the same, renders it a "new tobacco product" requiring premarket review.[6] On September 30, 2015, members of industry filed a lawsuit challenging, among other things, this policy and its procedural validity.[7] This challenge remains pending.

Nevertheless, the Agency's disputed document indicates that, in order to support a quantity change in an SE report, companies should submit "[s]cientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product compared to the predicate product."[8] As with modifications to flavoring ingredients, FDA appears to presume that all differences in quantity, both increases and decreases, alter consumer behavior in a negative way and then shifts the burden to the applicant to prove otherwise using scientific data. This evidentiary burden in the context of SE reports for mere quantity changes is unreasonable and inconsistent with Congressional intent. The FFDCA provisions regarding premarket approval applications (PMTAs) and modified risk tobacco product (MRTP) applications require data and information on the behavioral aspects of a tobacco product's use.[9] Congress did not, however, require such data to be submitted in conjunction with SE Reports. We must assume that omission was purposeful and reflects Congress's intent that the SE process should be more streamlined and less onerous than the processes for PMTAs or MRTP applications.

Conclusion

The substantial equivalence review process has proved to be overly burdensome, arbitrary, and inconsistent with statutory intent. FDA continues to be overwhelmed with the number of SE reports for currently regulated products now 55 months into the review process. Importantly, numerous products have been removed from the market thus far as a result of the SE process, a majority after pressure from FDA to withdraw pending reports in the face of overwhelming information requests and unreasonably short response deadlines. It is clear from the SE experience so far that FDA cannot subject newly deemed products to this regime without significant and meaningful changes to the process, including the issuance of clear and comprehensive guidance for each category of products following consideration of stakeholder comments and OIRA review.

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[6] FDA, *Guidance for Industry, Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)* at 17-18 (Sept. 8, 2015), *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf [hereinafter, "SE FAQ"].

[7] *See* Complaint for Declaratory and Injunctive Relief, Philip Morris USA Inc. v. FDA, 15-cv-01590 (D.D.C. Sept. 30, 2015).

[8] SE FAQ at 21

[9] *See* FFDCA §§ 910(c), 911(g)(2).

TTB Totals for YE December 2014

Cigarettes:				
Domestic Manufacture incl Puerto Rico		254,486,570,103		
Imported		8,194,703,000		
total cigarettes		262,681,273,103		
Cigars:				
Domestic Manufacture incl Puerto Rico		7,503,592,552		
Imported		6,190,960,000		
total cigars		13,694,552,552	5.21%	as a % of total cigarett
Approximate SKUs for SE applications for Cigarettes		5000		
Testing costs at $6,750 per sku	$	33,750,000		consider on per carton
per stick amount	$	0.0001285	200	0.025697
Approximate SKUs for SE applications for Cigars		13500	average of the 12K to 15K FDA pro	
Testing costs at $6,750 per sku	$	91,125,000		
per stick amount	$	0.006654		consider per carton
Difference per stick	$	0.006526	200	$ 1.31
% Difference		5079%		

es sold

jects

CITMA WORKING DRAFT 11/10/2015

PROPOSED STREAMLINED PATHWAYS FOR DEEMED PRODUCTS

1. Abbreviated PMTAs for ENDS Products - Framework

Congress designed the PMTA process for premarket review of "new" forms of traditional tobacco products. Thus, this pathway must be modified for products such as ENDS that fall on the opposite end of the risk continuum from combustible products and that Congress could not have contemplated when crafting the Family Smoking Prevention and Tobacco Control Act. FDA should provide additional flexibility with respect to PMTAs for ENDS products, while still appropriately protecting the public health, by establishing an abbreviated PMTA pathway for categories of products on the lower-risk end of the continuum. Because the Federal Food, Drug, and Cosmetic Act (FFDCA) provides FDA with broad discretion to determine if a PMTA, "along with any other information before the Secretary with respect to such tobacco product," demonstrates that "permitting such tobacco product to be marketed would be appropriate for the protection of the public health,"[1] FDA has the statutory authority to implement abbreviated PMTA procedures for certain categories of tobacco products.

This abbreviated PMTA pathway should consist of a "provisional approval" based on certain parameters, coupled with marketing conditions and postmarketing commitments. Such a regulatory approach was proposed by Dr. David Abrams early in 2014.[2] It should also provide for priority meetings with the Agency to discuss the required contents of the abbreviated PMTA, a rolling review of submissions, and a shorter time clock for review of applications. A failure to comply with the conditions of approval or any postmarketing commitments could result in enforcement action or withdrawal of provisional approval. In addition, FDA may withdraw approval of an abbreviated PMTA if it determines that, based on postmarketing data or other evidence, the product is no longer appropriate for the protection of the public health.

For instance, an abbreviated PMTA for an ENDS product could consist of the following:

1. Full reports of any investigations of health risks related to the new product or a comparable product in the possession of the applicant at the timing of filing;
2. A full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation;
3. A full description of methods of manufacturing and processing;
4. Results of constituent testing of liquid and vapor (consistent with applicable guidance from FDA), as applicable;
5. Samples of the product and its components;
6. Any marketing data or plans in the possession of the applicant for the product; and

[1] 21 U.S.C. § 387j(c)(2).

[2] Abrams DB. Promise and peril of e-cigarettes: can disruptive technology make cigarettes obsolete? JAMA 2014;311:135-136.

7. Specimens of current labeling and promotional materials and those intended for dissemination or publication within 120 days following issuance of a PMTA order.

FDA could condition the issuance of a marketing order on the following:

1. A demonstration that the product meets certain specified constituent testing and/or other manufacturing standards;
2. Compliance with any existing flavor standards developed by industry or the Agency; and
3. A commitment to:
    a. Submit samples of all promotional materials at least 30 days prior to the intended time of dissemination of the labeling or initial publication of the advertisement;
    b. Conduct certain postmarket surveillance and report postmarketing data at set time intervals as directed by FDA for at least three years; and
    c. Comply with reasonable conditions of approval on the labeling of the product as directed by FDA.

To receive provisional approval, an abbreviated PMTA application would include constituent testing of the liquid and vapor, but applicants would ***not*** be required to conduct new clinical or nonclinical studies on the new product that is the subject of the application, including in vitro or in vivo toxicology studies, abuse liability evaluations, carcinogenicity studies, use pattern/topography evaluations, clinical pharmacology investigations, human factors research, or studies comparing the new product to other tobacco products in terms of health effects.

Likewise, an abbreviated PMTA would ***not*** be required to contain consumer use studies, including those relating to the likelihood that consumers will adopt the new product and then switch to other tobacco products, the likelihood of consumers using the new product in conjunction with other tobacco products, or the likelihood of consumers switching to the new product instead of ceasing tobacco product use or using an FDA-approved tobacco cessation product. Abbreviated PMTA applicants would also ***not*** be required to study the likelihood that nonusers, including youth, may initiate with the new product. Rather, these consumer use and behavior issues will be explored via postmarket surveillance and data.

FDA should additionally provide for the flexibility to bundle multiple, related products into a single PMTA submission (e.g., various nicotine strengths and flavors, various size and package configurations). Furthermore, prior to requiring the submission of PMTAs for deemed products, FDA should, via guidance or regulation, establish a process for modifications to PMTA-approved ENDS products. FDA might use as a model its procedures for making changes to drug products approved under new drug applications (NDAs) or abbreviated NDAs.[3] As in the drug context, FDA should designate categories of changes to PMTA-approved ENDS products that may be made without prior FDA approval.

These alternative regulatory approaches would enable products that present lower relative risk such as ENDS to stay on the market subject to certain conditions while helping to generate the data and information needed for FDA to fully confirm the products' impact on the public health.

[3] *See* 21 C.F.R. § 314.70.

They would also set expectations that smaller ENDS companies could at least potentially meet, while still satisfying FDA's regulatory objectives, and allow for continued innovation. In that regard, before requiring the filing of abbreviated marketing submissions for currently marketed ENDS products, FDA should finalize and implement this policy sufficiently in advance (no less than one year) of the filing deadline.

2. Develop Standard Reference Products for Use as "Predicates" in SE Process

A large percentage of small deemed combustible product (cigar, pipe tobacco) manufacturers entered the market after February 2007. All ENDS product manufacturers and importers entered the market after February 2007. Accordingly, these companies do not have access to adequate information about a 2007 predicate product. In order to enable these small manufacturers to survive, FDA should establish standardized reference products for each sub-category (e.g., larger ring gauge cigars, filtered cigars, cigarillos, pipe tobacco, and hookah, as well as ENDS products, each with and without flavors, in various packaging configurations) to which manufacturers could compare their products in the context of an SE report in lieu of a grandfathered product. The combustible reference products could be based on typical products marketed in 2007 and information regarding those products could be obtained by the component suppliers. The ENDS reference product could be developed in a process similar to the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) process to develop a standardized electronic cigarette for use in clinical research. *See* SBIR Topic 156, Solicitation Number: N43DA-15-8921 (May 29, 2014). *Available at* https://www.fbo.gov/index?s=opportunity&mode=form&id=9d121f4da6d8ecec8e6e668c10050947&tab=core&tab mode=list&. FDA could publish the specifications for this reference product for use by manufacturers as a surrogate "predicate."

We acknowledge that FDA appears to have rejected a similar approach in the context of cigarettes. See, e.g., Technical Project Lead (TPL) Review for 4 R.J. Reynolds Tobacco Company products (SE0000276, SE0000277, SE000278, SE0000281) (9/11/15) (FDA advised RJR that its SE reports were deficient because they cited as a predicate "a composite of all cigarettes commercially marketed in the United States as of February 15, 2007" and therefore did not "fully identify the predicate product (i.e., how the predicate tobacco product is uniquely identified for a consumer such as brand, subbrand, size, quantity, and packaging).") We submit that because many more years have now passed since the 2007 grandfather date, FDA must reconsider this overly strict interpretation of the Act in the context of newly deemed products such as cigars, pipe tobacco, hookah and ENDS products. Moreover, rather than citing a "composite" of marketed products, this proposal envisions that FDA itself would establish the specifications for the standardized predicates. This approach would benefit public health because the Agency would have control over the specifications for the "predicate" reference product and therefore would be setting the base standard for comparison.

FDA has the statutory authority to establish a "predicate" product for the purposes of SE reports. Section 910 of the FFDCA states that the term "substantially equivalent" means "that the Secretary by order has found that the tobacco product – (i) has the same characteristics as the predicate tobacco product; or (ii) has different characteristics and the information submitted contains information … that demonstrates that it is not appropriate to regulate the product under

this section because the product does not raise different questions of public health." Importantly, however, the term "predicate tobacco product" is not defined in the FFDCA. Section 905(j) provides that a product that was not commercially marketed in the United States as of February 15, 2007, must submit a report demonstrating that the product is SE to a product commercially marketed in the U.S. as of February 15, 2007, or to a product that the Secretary has previously determined, pursuant to Section 910, is "substantially equivalent." Based on this latter phrase, FDA could establish a standardized "predicate tobacco product" and determine that all reasonably identical products are "substantially equivalent" to this standardized product because they have the same or substantially similar characteristics. For products that are not reasonably identical to the standardized predicate, an SE report would need to demonstrate that the new tobacco product does not raise different questions of public health than the products that have been determined by FDA to be substantially equivalent to (in this case, reasonably identical to) the standardized predicate product developed by the Agency.

Indeed, there is precedent for FDA approaching an overwhelming regulatory review task like this one in a very analogous way: the OTC Review. In 1962, Congress amended the FFDCA to add a requirement that drugs be shown to be effective as well as safe. In light of this new efficacy requirement, FDA had to determine how to regulate the hundreds of thousands of drugs that were already on the market and were not approved under an NDA that demonstrated both safety and effectiveness. For over-the-counter (OTC) drugs, of which there were an estimated 100,000 to 500,000 on the market, FDA decided in 1972 to establish the OTC monograph system, or OTC Review, to review the safety and effectiveness of OTC drugs by therapeutic category rather than rather than individually. 37 Fed. Reg. 85 (Jan. 5, 1972).

In deciding to proceed in this way, the Agency acknowledged:

> The limited resources of the Food and Drug Administration would be overwhelmed by attempting to review separately the labeling and the data on the safety and effectiveness for each OTC drug now on the market. This would be further complicated by the almost daily growth in the number of drugs being marketed and the changes in formulation and labeling of previously marketed drugs ... The prospects of completing a detailed drug-by-drug review of the OTC market in a reasonable time are extremely remote.

37 Fed. Reg. at 86. Of relevance here, FDA also observed:

> Practically all of the thousands of OTC drugs now marketed are compounded from only an estimated 200 active ingredients which are used either alone or in varying combinations. Many thousands of these drugs are readily comparable in that the labeling is similar and the active ingredients are the same, or are essentially the same, but are present in slightly different dosages.

Id.

Likewise, most cigars, pipe tobacco and hookah products on the market contain very similar ingredients and components to one another and most ENDS products on the market contain

liquids with similar ingredients and use common delivery device features. Permitting comparison to a standardized predicate product established by FDA would allow the Agency to review specific information about the product that is the subject of the SE report while comparing it to one singular standard. Like the OTC Review, this would enable the Agency to protect the public health in an efficient manner without bringing the Agency's SE review process to a virtual standstill and/or decimating the marketplace for the smaller industry players.

CITMA
COALITION OF INDEPENDENT TOBACCO MANUFACTURERS OF AMERICA

November 9, 2015

Via Overnight Delivery & Electronic Mail

Mitch Zeller, J.D.
Director
Center for Tobacco Products
Document Control Center (DCC)
9200 Corporate Blvd.
Room 020J
Rockville, MD 20850

Re: Apparent Leak of Deeming Regulation Documents

Dear Director Zeller:

On behalf of the Coalition of Independent Tobacco Manufacturers of America (CITMA), we express our members' grave concerns about the regulatory process used by the U.S. Food and Drug Administration (FDA) for exercising its so-called "deeming" authority to subject additional tobacco products to the controls of Chapter IX of the Federal Food, Drug, and Cosmetic Act. For the second time, it appears that the Tobacco Vapor Electronic Cigarette Association (TVECA), and through TVECA perhaps others, obtained a draft version of FDA's rule (and a related guidance document) prior to its official publication in the Federal Register. This *ex parte* communication with a small segment of the industry is procedurally infirm, contrary to law, and fundamentally unfair. In order to ensure a level playing field and cure the prejudice to other stakeholders, we hereby request that FDA immediately release to the public a copy of all leaked materials in the possession of TVECA. In the alternative, if FDA cannot determine which versions of which deeming documents TVECA possesses, we request that FDA release the draft version of the final deeming regulation transmitted to the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget.

FDA acknowledged the most recent apparent leak of its final deeming regulation[1] and the *ex parte* communications in which it engaged with TVECA regarding the matter. Significantly, this is the second reported leak to TVECA in this rulemaking process. In April 2014, FDA

[1] FDA, A Special Statement from CTP (Oct. 31, 2015), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm470409.htm.

acknowledged TVECA's claim that it had a copy of the proposed deeming regulation prior to publication.[2] At that time, counsel for CITMA spoke with the Center for Tobacco Products Ombudsman and requested an investigation of the apparent leak. To our knowledge, FDA never confirmed publicly that it conducted any investigation or took any other action in response to our request.[3] Now the situation has recurred at an even more critical juncture in the rulemaking process. It is deeply troubling that the Agency lacks transparency in this matter and that TVECA and perhaps others again appear to have obtained a draft version of the rule prior to its official publication.

We note that, in the event of prohibited *ex parte* communications in the rulemaking process, courts have required the withdrawal of the rule and further rulemaking activies.[4] This is especially true where the release of information violates the Agency's own rulemaking procedures. *See* 21 C.F.R. § 10.80(d)(2) (providing that a "draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the Federal Register").

Ex parte release of the final rule (and at least one companion guidance document) prior to publication, even if additional changes may be requested by OIRA, places all other stakeholders, including CITMA's small business members, at a significant competitive disadvantage. First, those with access to the full content of the regulations and related documents have effectively received advance notice of, and thus more time to comply with, the requirements set forth in the regulations relative to members of industry who must wait for the documents' official publication. For example, these noticed companies can conduct business and compliance planning activities to prepare for implementation of the rule. Second, those with access to the draft final rule can engage more effectively with OIRA, and other agencies participating in the OIRA review, to advance their agendas. Thus, in order to ensure a fair process and restore a level playing field, FDA must immediately grant the relief requested.

We additionally request that FDA conduct full investigations of both of these apparent leaks and publicly report the results. These events have shaken our confidence in the integrity and fairness of the deeming process and FDA's internal procedures. Thorough transparent investigations, as well the implementation of measures to address the apparent weaknesses in

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[2] FDA, A Special Statement from CTP (Apr. 18, 2014), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm394018.htm.

[3] On October 29, 2015, CITMA filed a request under the Freedom of Information Act seeking all documentation regarding FDA's April 2014 investigation, if any, but has not yet received a response.

[4] *E.g., Sangamon Valley Television Corp. v. United States*, 269 F.2d 221 (D.C. Cir. 1959) (invalidating a Federal Communications Commission (FCC) rule regarding television channel allocations where it was FCC practice to provide a cut off for comments and forbid the filing of additional comments unless requested by the Commission, but a commenter met with each Commissioner individually after that date).

FDA's internal document control processes, could help mitigate the damage done to date and improve public confidence in the integrity and fairness of FDA's regulatory activities.

Thank you for your consideration. We look forward to hearing from you.

Sincerely,

Kevin Altman /so/

Kevin Altman
Consultant, CITMA

cc: Ella Yeargin, CTP Ombudsman
Lindsay Tobias, Office of Policy
Elizabeth H. Dickinson, Chief Counsel